4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-1005]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Focus Groups and Interviews as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0497. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Focus Groups and Interviews as Used by the Food and Drug Administration

OMB Control No. 0910-0497--Extension

FDA conducts focus groups and in-depth individual interviews on a variety of topics involving FDA-regulated products, including drugs, biologics, devices, food, tobacco products, and veterinary medicine.

Focus groups are an important role in gathering information because they allow for a better understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies and encourages interaction between participants.

Individual interviews allow for a more comprehensive, in-depth information exchange where more insights are likely to be collected.

Both focus groups and in-depth individual interviews serve the narrowly defined need for direct and informal opinion on a specific topic and, as a qualitative research tool, have three major purposes:

- To obtain consumer information that is useful for developing variables and measures for quantitative studies,
- To better understand consumers' attitudes and emotions in response to topics and concepts, and
- To further explore findings obtained from quantitative studies.

FDA will use findings to test and refine ideas but will generally conduct further research before making important decisions, such as adopting new policies and allocating or redirecting significant resources to support these policies.

Respondents to this collection of information will include members of the general public, healthcare professionals, the industry, and other stakeholders who are related to a product under FDA's jurisdiction. Inclusion and exclusion criteria will vary depending on the research topic.

In the *Federal Register* of April 11, 2023 (88 FR 21680), FDA published a 60-day notice requesting public comment on the proposed collection of information. Three comments were

received, two in support of the information collection, and one that did not address the elements of the PRA.

FDA estimates the burden of this collection of information as follows:

Table 1—Estimated Annual Reporting Burden [1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Focus groups and individual in-depth interviews	12,000	1	12,000	1.75	21,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated burden for the information collection reflects an overall increase of 5,600 hours and a corresponding increase of 3,200 responses. We have added individual in-depth interviews as a method of information gathering. In addition, we are consolidating ICR 0910-0677, "Focus Groups About Drug Products as Used by the Food and Drug Administration" into this request for extension.

Dated: October 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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